K012004

SEP 2 5 2001

June 26, 2001

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92

1. SUBMITTER INFORMATION

a. Company Name:	SenoRx Inc.
b. Company Address:	11 Columbia, Suite A
c. Telephone: Facsimile:	(949) 362-4800 (949) 362-3519
d. Contact Person:	Amy Boucly Director, Regulatory Affairs and Quality Assurance
e. Date Summary Prepared:	June 26, 2001

2. DEVICE IDENTIFICATION

a. Trade/Proprietary Name:	Easy Guide™ Electrosurgical Access Device
b. Classification Name:	Electrosugical cutting and coagulation device and accessories, 21 CFR 878.4400

3. IDENTIFICATION OF PREDICATE DEVICES

Sure Core Biopsy Electrode	Interventional Concepts, Inc. K963813
Accucise Electrosurgical Trocar	Applied Medical Resources K925984
Bovie Hand Control	Sybron Corporation K790187

4. DESCRIPTION OF THE DEVICE

The SenoRx Easy Guide™ Electrosurgical Access Device consists of a monopolar electrosurgical trocar used to penetrate the breast, and a cannula to provide a passageway through which a breast biopsy instrument may be placed.

5. STATEMENT OF INTENDED USE

The Easy Guide™ is indicated for use in diagnostic breast biopsy procedures to penetrate the breast under ultrasound guidance and provide a passageway through which a diagnostic biopsy of a breast may be performed.

6. COMPARISON WITH PREDICATE DEVICES

The intended use, design, construction, materials and technology are comparable to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 5 2001

Ms. Amy Boucly
Director, Regulatory Affairs
And Quality Assurance
SenoRx, Inc.
11 Columbia
Suite A
Aliso Viejo, California 92656

Re: K012004
Trade/Device Name: SenoRx EasyGuide™ Electrosurgical Access Device
Regulation Number: 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: July 26, 2001
Received: July 27, 2001

Dear Ms. Boucly:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2 FDA Indications for Use Page

510(k) number (if known): K012004

Device Name: **Easy Guide™ Electrosurgical Access Device**

Indications for Use: The Easy Guide™ Electrosurgical Access Device is indicated for use to penetrate the breast under ultrasound guidance and provide a passageway through which a diagnostic biopsy of a breast may be performed.

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K012004

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)